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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,244	06/27/2001	Barry S. Fogel	SOMX.18CP1DV1	4907

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/893,244	FOGEL, BARRY S.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 85-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 85-88 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/30/07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Response to Arguments

Claims 85-88 have not been amended or changed and are currently amended.

The applicant's have presented a 1.132 declaration by Barry S. Fogel, M.D. in support of their assertions of unexpected results. It is deemed non-persuasive.

The 1.132 declaration is similar to the 1.132 declaration presented on 10/21/2006. The differences come in paragraphs 5 and 6 of the present declaration wherein the magnesium administered is "...chelated magnesium equivalent to 300mg of elemental magnesium...". In the declaration of 10/21/2006 the magnesium administered is "...magnesium oxide equivalent to 250mg of elemental magnesium...". In the present declaration, in paragrpah 6, all reference to the 46 year old man of the Case Report 5 in US Patent Application 09/893244 is removed and is replaced with a non-descript report of treatment of another 46 year old man that is treated identically to the Case Report 5 46 year old man with acamprosate with the exception that the 46 year old man is now additionally treated with magnesium oxide at a dosage of 250 mg elemental magnesium versus the Case Report 46 year old man that received chelated magnesium oxide at a dosage equivalent to 300 mg elemental magnesium.

While the examiner finds the information presented interesting it is not sufficient to overcome the rejections. The fact that the applicant did not find magnesium in any of the forms tested active in the present composition and subsequent increased activity of

a combination of acamprosate (an NMDA antagonist) with magnesium (a known NMDA antagonist) does not provide sufficient evidence to prove synergism. For the reasons above and for the reasons of record the 103(a) rejection of the previous office action is maintained and restated below. **This action is made final.**

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidsky (US Patent No. 5602150), in view of Vetulani (Review Drug Addiction. Part III. Pharmacotherapy of Addiction, Polish Journal of Pharmacology, 2001, Vol. 53, pp. 415-434), in view of Bormann et al. (US Patent No. 5061703) and further in view of Decollogne et al. (NMDA Receptor Complex Blockade by Oral Administration of Magnesium: Comparison with MK-801, 1997, Pharmacology Biochemistry and Behavior, Vol. 58, No. 1, pp. 261-268).

Lidsky et al. teach in, the abstract and col. 10 lines 35-65, a method of treatment and a composition to prevent the development of the adverse manifestation of tardive dyskinesia in patients undergoing treatment with a neuroleptic or antipsychotic agent comprising administering the neuroleptic or antipsychotic agent with taurine, a taurine precursor, taurine derivative, or compounds similar in action to taurine including acamprosate (as evidenced by applicant's own admission, see current specification page 23, line 25).

Lidsky does not teach that acamprosate is to be administered with a second active moiety comprising an NMDA-type glutamate antagonist, nor exactly by what mechanism acamprosate and the other taurine derivatives work.

Vetulani teaches, on page 424, that acamprosate acts as both a GABAergic neurotransmitter enhancer and as an antagonist of glutamatergic neurotransmission via the NMDA receptor. Thus acamprosate is both a GABA agonist and a NMDA antagonist.

Decollogne et al. teach, in the abstract and on page 265, that oral treatment with a single dose of magnesium organic salts (such as magnesium aspartate, magnesium lactate) leads to an increase in serum Mg2+ concentration and that magnesium is a noncompetitive ion-channel blocker of the NMDA receptor complex.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made that acamprosate (a GABA agonist and NMDA-receptor antagonist and magnesium (an NMDA-receptor antagonist) targeted the same receptor pathways. Additionally Lidsky demonstrated that acamprosate was effective in the prevention of tardive dyskinesia associated with neuroleptic and antipsychotic drugs. One of ordinary skill would know that compounds targeting the same receptor have similar activities and could be used in the treatment of similar conditions.

The examiner respectfully points out the following from MPEP 2144.06:
"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from

their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER